CLAIMS

What is claimed is:

1. A method of making risedronate sodium, substantially free of iron, comprising:

refluxing a combination comprising risedronic acid, a sodium base, and an iron-reducing amount of EDTA in a liquid; and

isolating risedronate sodium substantially free of iron from the combination.

2. The method of claim 1, wherein the sodium base is sodium hydroxide.

3. The method of claim 1, wherein the sodium base in the combination is of an amount such that the ratio of the number of moles of sodium base to the number of moles of risedronic acid in the combination is between about 1:0.8 and about 1:1.2.

4. The method of claim 3, wherein the ratio of moles of sodium base to moles of risedronic acid is between about 1:1 and about 1:1.2.

5. The method of claim 1, wherein the iron-reducing amount of EDTA is between about 5% and about 50% of the risedronic acid on a dry per-weight basis.

6. The method of claim 5, wherein the iron-reducing amount of EDTA is between about 5% and about 20% of the risedronic acid on a dry per-weight basis.

7. The method of claim 1, wherein the liquid is selected from the group consisting of water, a lower alkanol, and a mixture of a lower alkanol and water.

8. The method of claim 7, wherein the liquid is about 40% to about 60%, v/v, of a lower alkanol in water.

9. The method of claim 8, wherein the liquid is about 50%, v/v, of a lower alkanol in water.

10. The method of claim 1, wherein the combination is refluxed until the pH is between about 4 and about 5.

11. The method of claim 10, wherein the combination is refluxed until the pH is between about 4.2 and about 4.7.

12. The method of claim 1, wherein during the refluxing step, the combination is subjected to shear forces.

13. The method of claim 12, wherein during the refluxing step, the combination is subjected to mechanical agitation.

14. The method of claim 1, further comprising cooling the refluxed combination after the refluxing step.

15. The method of claim 14, wherein the refluxed combination is cooled to a temperature between about 0°C and about 30°C

16. The method of claim 1, wherein the amount of metal in the isolated risedronate sodium is at least about 30% to about 50% lower than the amount of metal in risedronate sodium made by the method of claim 1 without a metal-reducing amount of EDTA.

17. The method of claim 1, wherein the liquid is a mixture of ethanol and water, and the obtained risendronate sodium is crystalline Form B.

18. Risedronate sodium made by the method of either of claims 1 or 17.

19. A method of treating bone loss comprising administering a pharmaceutical formulation comprising risedronate sodium made by the method of either of claims 1 or 17.

20. A pharmaceutical composition comprising at least one pharmaceutically acceptable excipient and risedronate sodium made by the method of either of claims 1 or 17.

21. Risedronate sodium substantially free of iron.

22. The risendronate sodium of claim 21, wherein the risedronate sodium is Form B.

23. Risendronate sodium containing less than about 50ppm of iron.

24. The risendronate sodium of claim 23, wherein the risedronate sodium is Form B.